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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,470

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Satoshi Takasaka

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,470	<b>Applicant(s)</b> TAKASAKA, SATOSHI	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Currently, claims 1-3 and 9-11 are pending.

#### ***Response to Arguments***

Applicant's arguments filed on 7/1/2008 have been fully considered. In particular, Applicants argue that the Jain reference does not teach that sildenafil can be used to treat any type of spinal cord injury pain and reports that sildenafil reduces peripheral nociceptive pain and does not affect central nociceptive pain. Applicants further argue that Cardenas teaches spinal cord injury as neurologic pain and not musculoskeletal pain.

In response to the above arguments, it is noted that the Jain reference was used to teach that sildenafil treats pain in general and in particular nociceptive pain. However, it is disagreed that Cardenas teaches spinal cord injury as being associated with only neurologic pain. Cardenas teaches that categorizing pain associated with spinal cord injury involves classification systems that include musculoskeletal pain and visceral pain in addition to neuropathic type pains (see Introduction). Further, Cardenas provides a study showing that patients with spinal cord injury report both types of pain (neurologic or neuropathic and musculoskeletal). As discussed previously, Putzke et al. (of record) teaches different forms of pain associated with spinal cord injury which includes such feelings of aching, cramping and dull as being forms of musculoskeletal pain. Therefore, spinal cord injury is not only associated with neurologic type pain but also with musculoskeletal pain. The above arguments are also applied towards to the 35 USC 103 rejection over Jain in view of Cardenas and further in view of Maw which

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provides the teaching that sildenafil can be formulation into an oral composition, because Applicants argue that because they feel that the combination of Jain and Cardenas is not obvious that Maw does not provide obviousness.

Accordingly, the rejections are maintained and are given below for Applicant's convenience.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med Rehabil, Vol. 83, Dec. 2002).

Jain et al. teach that sildenafil is a cGMP PDE5 inhibitor that is useful in the treatment of pain, in particular peripheral antinociception (see in particular results and figures).

Jain et al. does not specifically teach that sildenafil or cGMP PDE5 inhibitors treat somatic pain in a patient suffering from spinal cord injury.

Cardenas et al. teach that chronic pain is associated with spinal cord injury (see whole document). Types of pain include musculoskeletal pain which is a type of

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somatic pain (see first paragraph on page 1708). Further, spasticity is associated with the musculoskeletal system in which muscles are continuously contracted and causes pain.

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and is useful in the treatment of peripheral pain, of which somatic pain is part of peripheral pain because it is not associated with the central nervous system, with Cardenas et al. which teach that pain is associated with spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al., with Cardenas et al. because the prior art teaches that sildenafil treats peripheral or somatic pain and spinal cord injury is associated with pain.

Claims 2-3 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med Rehabil, Vol. 83, Dec. 2002) as applied to claim 1 above, and in further view of Maw et al. (U.S. Patent 6,856,439).

Jain et al. and Cardenas et al. teach that sildenafil treats somatic pain and that pain is associated with spinal cord injury.

Jain et al. and Cardenas et al. do not teach the route of administration or the dosage of sildenafil.

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Maw et al. teach a pharmaceutically active compound comprised of a cGMP PDE5 inhibitor that is used to treat various disorders, including female sexual pain disorder and sexual dysfunction due to spinal cord injury (Col. 25, lines 13-20). They further teach that the compound will be administered orally (encompassing claim 2, Col. 25, lines 52-53) and a dose range of tablets as being between 0.01 mg and 500 mg (encompassing claim 3; Col. 27, lines 30-31).

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and Cardenas et al. which teach that spinal cord injury is associated with pain, with the teachings of Maw et al. which teach a composition comprised of a cGMP PDE5 inhibitor to treat various disorders, including female sexual pain disorder and sexual dysfunction in patients suffering from spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al. and Cardenas et al. with Maw et al. to obtain an efficacious compound to alleviate pain associated with spinal cord injury.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617